



U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

August 6, 2019

IN THE MATTER OF

Oak Hill Hometown Pharmacy
819 Main Street East
Oak Hill, West Virginia 25901-3123

Certificate of Registration Number FO3507223

**ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION**

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21,
United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Oak Hill Hometown Pharmacy ("OHHP") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration ("COR") number FO3507223, pursuant to 21 U.S.C. § 824(d), because OHHP's continued registration constitutes "an imminent danger to the public health or safety." Notice is also given to afford OHHP an opportunity to show cause before the DEA in Arlington, Virginia, or at a location designated by the Administrative Law Judge, on October 15, 2019, (if OHHP requests such a hearing), as to why the DEA should not revoke OHHP's registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registrations, or for additional DEA registrations, because OHHP's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f).

As detailed below, this order states the DEA's basis for this Order to Show Cause and Immediate Suspension of Registration, including a *non-exhaustive summary* of facts and law at issue, as well as citations to laws and regulations that OHHP has violated (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which the DEA construes *in pari materia*). In order to preserve OHHP's rights in this proceeding, OHHP must appear in these revocation proceedings by filing a notice of appearance or request for hearing in the manner prescribed by regulations within 30 days from the receipt of this Order.

1. OHHP is registered with the DEA to handle controlled substances in Schedules II through V under DEA COR number FO3507223. OHHP's registered address is at 819 Main Street East, Oak Hill, West Virginia 25901-3123. OHHP's DEA COR expires by its own terms on December 31, 2021.
2. Martin Njoku is the owner and pharmacist-in-charge of OHHP.
3. OHHP is presently licensed in the State of West Virginia as a retail pharmacy with license number SP0552435. OHHP's state pharmacy license expires by its own terms on June 30, 2020.
4. OHHP's DEA COR should be revoked and any pending application should be denied because OHHP has committed such acts as would render its registration inconsistent with the public interest, as that term is defined under the Controlled Substances Act. *See* 21 U.S.C. § 824(a)(4); 21 U.S.C. § 823(f). As explained in greater detail below, an independent pharmacy expert retained by the DEA has reviewed numerous prescriptions filled by OHHP, and has concluded that OHHP repeatedly issued prescriptions in violation of the minimum practice standards that govern the practice of pharmacy in West Virginia. Specifically, from at least December 2016 through at least March 2019, OHHP repeatedly filled prescriptions for Schedule III narcotics in the face of obvious red flags of drug abuse and diversion, and, therefore, in violation of both federal and West Virginia law, including 21 C.F.R. §§ 1306.06 and 1306.04(a), and W. Va. Code § 60A-3-308(c).

LEGAL REQUIREMENTS

5. A "prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." 21 C.F.R. § 1306.06. A pharmacist is only permitted to fill a prescription that was "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Although "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* Section 1306.04(a) "prohibit[s] a pharmacist from filling a prescription for a controlled substance when she either knows or has reason to know that the prescription was not written for a legitimate medical purpose." *Wheatland Pharmacy*, 78 Fed. Reg. 69,441, 69,445 (2013) (internal quotations and alterations omitted). Section 1306.04(a) "expressly requires pharmacists to identify and resolve suspicions that a prescription is illegitimate." *Trinity Pharmacy II*, 83 Fed. Reg. 7,304, 7,331 (2018).
6. A violation of these federal regulations is a violation of federal law. *See* 21 U.S.C. § 842(a)(1) (making it unlawful to dispense controlled substances in violation of 21 U.S.C. § 829, whose scope is defined in part by 21 C.F.R. §§ 1306.04, 1306.06). Moreover, any attempt to violate these federal regulations is a violation of federal law. *See* 21 U.S.C. § 846. Additionally, the DEA may find that a registrant's DEA COR is inconsistent with the public interest if the registrant acted carelessly or negligently in handling controlled substances, even if the registrant did not intend to violate the

Controlled Substances Act. *See, e.g., The Medicine Shoppe*, 79 Fed. Reg. 59,504, 59,506 (2014) (quoting *Paul J. Caragine, Jr.*, 63 Fed. Reg. 51,592, 51,601 (1998) (“Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify revocation or denial.”)).

7. In addition to the above federal regulations, OHHP and its pharmacists must comply with applicable West Virginia law, including W. VA. CODE § 60A-3-308(c), which states that Schedule III controlled substances “shall not be dispensed without a lawful prescription of a practitioner.”

IMPROPER DISPENSING

8. From at least December 2016 to March 2019, OHHP’s pharmacists filled approximately 2,000 prescriptions for a widely-abused Schedule III narcotic, Subutex, in the face of obvious red flags of drug abuse and diversion. Over half of these prescriptions came from a clinic in Waynesburg, Pennsylvania—A&R Solutions—that is located approximately 180 miles northeast of OHHP. OHHP’s customers traveled significant distances—in some cases, more than 600 miles—to obtain and fill their prescriptions, and many of them made frequent trips to OHHP to obtain partial fills of their prescriptions, which they paid for in cash. The DEA consulted an independent pharmacy expert who opined that the red flags presented by these prescriptions were so strongly indicative of drug abuse and diversion that they could not have been resolved by a pharmacist acting in the usual course of professional practice. Therefore, these prescriptions violated state and federal law.
9. In addition to more recent misconduct, *see* paragraphs 11-15, *infra*, the DEA’s expert opined that from December 14, 2016 to November 28, 2018, OHHP filled approximately 2,000 prescriptions that presented the following unresolvable red flags of drug abuse and diversion:
 - a. **The Prescriptions Were For Subutex, A Widely-Abused Drug:** All of these prescriptions were for Subutex, a brand name drug containing buprenorphine. Buprenorphine is a Schedule III narcotic that is primarily used to treat narcotic addiction. The DEA’s expert opined that, because buprenorphine is an opioid derivative, it has a significant risk of abuse and diversion. To prevent buprenorphine from being abused, it is frequently combined with naloxone, which is an opioid antagonist that blocks or reverses the effects of opioids if the user attempts to abuse the drug. The DEA’s expert opined that, because buprenorphine/naloxone combination products (*e.g.*, Suboxone) have a lower abuse potential than buprenorphine-only products (*e.g.*, Subutex), buprenorphine/naloxone combination products should always be prescribed as the first-line treatment for narcotic addiction, unless the patient is pregnant or allergic to naloxone.¹ Accordingly, the DEA’s expert opined that a pharmacist should not

¹ *See, e.g., Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*, U.S. Department of Health and Human Services’ Substance Abuse and Mental Health

fill a Subutex prescription unless the patient is pregnant or allergic to naloxone. The DEA's expert opined that it is highly unlikely that all of the patients who filled these 2,000 Subutex prescriptions were pregnant or allergic to naloxone. Approximately half of these prescriptions were written for men, who could not have been pregnant, and the DEA's expert opined that it is highly unlikely that all of these men were allergic to naloxone, because naloxone allergies are uncommon.

- b. **The Prescriptions Were Issued By Out-Of-State Physicians:** All of these prescriptions were issued by Pennsylvania prescribers to residents of southern West Virginia, who lived an average of approximately 190 miles from the prescribers' offices. The DEA's expert opined that it can be a red flag of abuse and diversion if a patient travels a significant distance to a physician's office, especially if that patient is not seeking specialized medical treatment, which these patients were not. They were all receiving Subutex (buprenorphine-only), which may be prescribed by any physician who has been designated by the DEA as a DATA waived physician. West Virginia has hundreds of DATA waived physicians who are permitted to prescribe buprenorphine products,² so it was a major red flag that so many patients were traveling such long distances to obtain Subutex.
- c. **Approximately 96 percent Of These 2,000 Prescriptions Were Paid For In Cash:** The DEA's expert opined that cash payments can be a red flag of abuse or diversion because patients typically have to pay very high prices for drugs that are not covered by insurance.
- d. **The Patients Traveled Long Distances To Fill Their Prescriptions at OHHP, And They Traveled To OHHP Frequently To Obtain Partial Fills:** A majority of these patients traveled long distances to fill their Subutex (buprenorphine-only) prescriptions at OHHP. Approximately 60 percent lived 30 or more miles from OHHP, and approximately 35 percent lived 50 or more miles from OHHP. The DEA's expert opined that it can be a red flag of abuse and diversion if a patient travels a significant distance to a specific pharmacy, especially if the patient also travels a significant distance to a particular prescriber. The DEA's expert also noted that OHHP's customers made frequent

Services Administration, 2004; *National practice Guidelines for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, American Society of Addiction Medicine, 2015.

² See Buprenorphine Practitioner Locator, U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration, https://www.samhsa.gov/medication-assisted-treatment/practitioner-program-data/treatment-practitioner-locator?field_bup_physician_us_state_value=WV&page=10. From December 2016 to November 2018, OHHP filled prescriptions for at least 36 Data waived physicians in West Virginia.

partial fills of their prescriptions. The DEA's expert opined that obtaining partial fills can be a red flag of abuse and diversion, especially when customers are purchasing a drug with a high street value, paying in cash, and traveling long distances to obtain and fill their prescriptions. The following are examples of patients who traveled long distances to their prescribers' offices and to OHHP, and obtained multiple partial fills of each prescription:

- i. **Patient N.J.:** From December 2016 to November 2018, Patient N.J.³ obtained 26 Subutex (buprenorphine-only) prescriptions from six different prescribers at A&R Solutions, whose offices were up to 180 miles northeast of her home. Patient N.J. filled these prescriptions at OHHP, which is approximately 50 miles southwest of her home. She made the 100-mile round trip drive to OHHP 139 times during this timeframe to obtain partial fills of these prescriptions, and she always paid in cash. Patient N.J. obtained up to seven partial fills per prescription, meaning that she traveled up to 1,000 miles to obtain and fill each prescription.
- ii. **Patient J.S.A.:** From September 2017 to November 2018, Patient J.S.A.⁴ obtained 15 Subutex (buprenorphine-only) prescriptions from a prescriber in Washington, Pennsylvania, approximately 170 miles northeast of his home. Patient J.S.A. filled these prescriptions at OHHP, which is approximately 25 miles southwest of his home. Patient J.S.A. made the 50-mile round trip drive to OHHP on 57 separate occasions to obtain partial fills of these prescriptions. On average, Patient J.S.A. traveled approximately 530 miles to obtain and fill each prescription.
- iii. **Patient M.H.:** From December 2016 to November 2018, Patient M.H. obtained 18 Subutex (buprenorphine-only) prescriptions from 13 different prescribers in Pennsylvania, seven of whom were from A&R Solutions. The prescribers' offices were up to 250 miles northeast of Patient M.H.'s home, and she filled these prescriptions at OHHP, which is approximately 45 miles southwest of her home. Patient M.H. made the 90-mile round trip drive to OHHP 45 times during this timeframe to obtain partial fills of these prescriptions. Patient M.H. obtained up to three partial fills of each prescription, and traveled up to 780 miles to obtain and fill each prescription.

³ See also ¶ 9.g.ii., *infra*.

⁴ See also ¶¶ 9.g.iii. and 15.a., *infra*.

- iv. **Patient C.P.:** From July 2017 to January 2018, Patient C.P. received eight Subutex (buprenorphine-only) prescriptions from four different prescribers at A&R Solutions, which is approximately 160 miles northeast of his home. Patient C.P. filled these prescriptions at OHHP, which is approximately 25 miles southwest of his home. Patient C.P. made the 50-mile round trip drive to OHHP on 25 separate occasions to obtain partial fills of these prescriptions. Patient C.P. obtained up to five partial fills of each prescription, and traveled up to 570 miles to obtain and fill each prescription.
 - v. **Patient J.J.1.:** From January 2017 to December 2017, Patient J.J.1. obtained 12 Subutex (buprenorphine-only) prescriptions from four different prescribers in Rochester, Pennsylvania, whose offices were approximately 240 miles northeast of her home. Patient J.J.1. filled these prescriptions at OHHP, which is approximately four miles southwest of her home. Patient J.J.1. traveled to OHHP on 69 separate occasions during this time frame to obtain partial fills of these prescriptions, and she paid for each prescription in cash. Although Patient J.J.1. did not travel significant distances to OHHP, Patient J.J.1. traveled up to 510 miles to obtain and fill each prescription, and the DEA's expert opined that it was a red flag that Patient J.J.1. obtained such frequent partial fills. Patient J.J.1. obtained an average of six partial fills per prescription, and she returned to OHHP every one to eight days during this one-year period to obtain these partial fills.
- e. **The Patients Traveled Out Of State For Buprenorphine-Only Products:** The DEA's expert opined that West Virginia residents appeared to be seeking out medical professionals in Pennsylvania because they were willing to prescribe Subutex (buprenorphine-only), which is easier to abuse and divert than Suboxone (buprenorphine/naloxone). The Prescription Drug Monitoring Report for OHHP, which records all of the controlled substance prescriptions that OHHP fills, indicates that Pennsylvania medical professionals prescribed Subutex much more frequently than West Virginia medical professionals. Out of the over 2,000 buprenorphine prescriptions that OHHP received from Pennsylvania prescribers, approximately 97 percent were for Subutex, and only three percent were for Suboxone. The DEA's expert opined that a ratio of 97 Subutex prescriptions to three Suboxone prescriptions is highly suspicious, and indicates that these prescriptions were not issued for a legitimate medical purpose, especially because approximately 50 percent of the customers who filled the Subutex prescriptions were men, whose only legitimate reason for receiving Subutex is a naloxone allergy. By contrast, during this same time frame, only two percent of the buprenorphine prescriptions that OHHP received from West Virginia prescribers were for Subutex, and the remaining 98 percent were for Suboxone.

- f. **OHHP Filled A High Volume Of Prescriptions With The Same Red Flags:**
During this time period, OHHP filled an average of seven Subutex (buprenorphine-only) prescriptions per day from Pennsylvania prescribers. The majority of these prescriptions emanated from A&R Solutions, a clinic in Waynesburg, Pennsylvania, that is located approximately 180 miles northeast of OHHP. OHHP frequently filled three or more Subutex prescriptions per day from prescribers at A&R Solutions. The DEA's expert opined that this consistent traffic from Pennsylvania, and specifically from A&R Solutions, should have been a major red flag for OHHP pharmacists.
- g. **The Pennsylvania Prescribers Appeared To Be "Pattern Prescribing":**
Multiple patients frequently presented prescriptions to OHHP that had been written on the same day, by the same prescriber, at the same clinic, for the same drug. The DEA's expert opined that "pattern prescribing" is a red flag of abuse and diversion that pharmacists must monitor for, and it refers to a physician who prescribes widely-abused drugs, often in the same dosages and quantities, to many patients. "Pattern prescribing" is a red flag of abuse and diversion because it indicates that the physician is focused on distributing drugs with high street value rather than on examining his patients and developing individualized treatment. On numerous occasions, including the following, OHHP filled prescriptions for physicians who were "pattern prescribing":
- i. On October 13, 2018, four patients (Patients B.C.1., R.C., M.L.H.,⁵ and C.S.) filled Subutex (buprenorphine-only) prescriptions at OHHP that they had all received from Prescriber F.K. on the same day. Prescriber F.K. works at A&R Solutions, which is approximately 180 miles northeast of OHHP.
 - ii. On July 29, 2017, five patients (Patients W.F., N.J.,⁶ R.M., S.D., and R.L.M.) filled Subutex (buprenorphine-only) prescriptions at OHHP that they had all received from Prescriber J.M. on the same day. Prescriber J.M. also works at A&R Solutions. On at least 12 additional occasions, three or four of these patients filled Subutex prescriptions at OHHP that they had received from Prescriber J.M. on the same day.
 - iii. On at least three separate occasions (July 26, 2018; September 20, 2018; and November 15, 2018), five patients (Patients J.S.A.,⁷ J.A., B.C.2., A.M., and J.W.) filled Subutex (buprenorphine-only) prescriptions that they had all received from Prescriber C.B. on the same day. Prescriber C.B.'s office is in Washington, Pennsylvania, approximately 200 miles northeast of OHHP. On at least ten additional occasions, three or four of

⁵ See also ¶ 12.c.ii., *infra*.

⁶ See also ¶ 9.d.i., *supra*.

⁷ See also ¶¶ 9.d.ii., *supra*, and 15.a., *infra*.

these patients filled Subutex prescriptions at OHHP that they had received from Prescriber C.B. on the same day.

- iv. On July 9, 2018, four patients (Patients R.M.D., S.H., M.V., and R.W.) filled Subutex (buprenorphine-only) prescriptions at OHHP that they had all received from Prescriber R.T. on the same day. Prescriber R.T.'s office is in Monroeville, Pennsylvania, approximately 225 miles northeast of OHHP.
10. The DEA's expert reviewed the above prescriptions and concluded that they presented numerous red flags that were highly indicative of abuse and diversion. These red flags could not have been resolved by a pharmacist acting in the usual course of professional practice, and, therefore, each prescription was filled outside the standard of care in West Virginia.

ONGOING CONDUCT

11. OHHP has continued to fill prescriptions for Subutex, a Schedule III controlled substance, in the face of obvious red flags of abuse and diversion through at least March 2019.
12. The DEA executed an Administrative Inspection Warrant ("AIW") at OHHP on November 28, 2018, and the DEA investigators interviewed several of OHHP's pharmacists, including Martin Njoku, the owner and pharmacist-in-charge. The investigators questioned OHHP's pharmacists about why OHHP filled so many prescriptions from Pennsylvania prescribers. In the weeks following the execution of the AIW, OHHP temporarily curtailed the filling of out-of-state Subutex (buprenorphine-only) prescriptions. However, OHHP pharmacists have since resumed filling prescriptions with the same unresolvable red flags of abuse and diversion outlined above, in paragraph nine. The DEA's expert reviewed 43 prescriptions that OHHP filled from December 2018 to March 2019, and opined that these prescriptions continued to present the following unresolvable red flags of abuse and diversion:

- a. **The Prescriptions Were For Subutex, A Widely-Abused Drug:** All of these prescriptions were for Subutex (buprenorphine-only). The DEA's expert opined that Subutex has a significant potential for abuse and diversion, and should only be prescribed to patients who are pregnant or allergic to naloxone. Twenty-one of these prescriptions (approximately 50 percent) were written for men, who could not have been pregnant. The DEA's expert opined that it is highly unlikely that all of these men were allergic to naloxone because naloxone allergies are uncommon. Additionally, if these patients had documented naloxone allergies, then they should have been able to obtain Subutex from West Virginia prescribers, rather than having to drive hundreds of miles to obtain it from Pennsylvania prescribers.

- h. **The Prescriptions Were Issued By Out-Of-State Physicians:** Twenty-six of these prescriptions (approximately 60 percent) were written by Pennsylvania prescribers. As discussed in more detail above, the DEA's expert opined that it can be a red flag of abuse or diversion if a patient travels a significant distance to a specific physician's office, especially if the patient is not seeking specialized medical treatment. These patients were not seeking specialized medical treatment. They were all receiving Subutex (buprenorphine-only), which may be prescribed by any physician who has been designated by the DEA as a DATA waived physician.
- b. **Patients Traveled Long Distances To Obtain And Fill Their Prescriptions, And They Obtained Frequent Partial Fills:** The DEA's expert opined that it can be a red flag of abuse and diversion if a patient travels a significant distance to a specific pharmacy, especially if the patient also travels a significant distance to the prescriber's office. The DEA's expert also opined that it can be a red flag of abuse and diversion if a patient has a pattern of obtaining partial fills of a drug with a high street value, and paying for the partial fills in cash. Numerous OHHP customers, including the following, traveled significant distances to obtain and fill their prescriptions, and frequently obtained partial fills of their prescriptions:
- i. **Patient J.J.2.:** From November 2018 to March 2019, Patient J.J.2. received five Subutex (buprenorphine-only) prescriptions from a prescriber in Waynesburg, Pennsylvania, whose office was approximately 150 miles northeast of her home. Patient J.J.2. filled these prescriptions at OHHP, which is approximately 35 miles southwest of her home. Patient J.J.2. made the 70-mile round trip drive to OHHP on more than 30 separate occasions to obtain partial fills of these prescriptions. Patient J.J.2. obtained up to eight partial fills of each prescription, and traveled up to 860 miles to obtain and fill each prescription.
 - ii. **Patient M.L.H.:** On November 10, 2018, Patient M.L.H.⁸ received a Subutex prescription from a prescriber in Pittsburgh, Pennsylvania, whose office is approximately 200 miles from her home. Patient M.L.H. filled this prescription at OHHP, which is approximately 25 miles southwest of her home. Patient M.L.H. made the 50-mile round-trip drive to OHHP on four separate occasions to obtain partial fills of this prescription. Patient M.L.H. traveled approximately 800 miles to obtain and fill this prescription.
 - iii. **Patient N.R.:** In November and December 2018, Patient N.R. received two Subutex (buprenorphine-only) prescriptions from a prescriber in Washington, Pennsylvania, whose office is approximately 150 miles northeast of her home. Patient N.R. filled these prescriptions at OHHP, which is approximately 70 miles southwest of her home. Patient N.R.

⁸ See also ¶ 9.g.i., *supra*.

made the 140-mile round trip drive to OHHP on two separate occasions to obtain partial fills of each prescription. Patient N.R. traveled approximately 580 miles to obtain and fill these prescriptions.

- c. **Approximately 86 percent Of These Prescriptions Were Paid For In Cash:** Thirty-seven of these prescriptions (approximately 86 percent) were paid for in cash. The DEA's expert opined that cash payments can be a red flag of abuse and diversion because patients typically have to pay very high prices for drugs that are not covered by insurance.

13. The DEA's expert reviewed the above prescriptions and concluded that they presented numerous red flags that were highly indicative of abuse and diversion. These red flags could not have been resolved by a pharmacist acting in the usual course of professional practice, and, therefore, each prescription was filled outside the standard of care in West Virginia.

NO LEGITIMATE NEED FOR SUBUTEX

14. As discussed in more detail above, OHHP temporarily curtailed its filling of out-of-state Subutex (buprenorphine-only) prescriptions after the AIW was served on November 28, 2018. This was, in part, because some of OHHP's customers began to fill their prescriptions at other pharmacies after they were notified by the federal government that their records had been seized from OHHP during the AIW.⁹ This was also, in part, because some of OHHP's customers who had been receiving Subutex began taking Suboxone (buprenorphine/naloxone) after the AIW was served. The DEA's expert opined that the fact that these patients switched to Suboxone after the AIW indicates that they never had a legitimate reason to be receiving Subutex, and that OHHP should not have filled their prescriptions.

15. The DEA's investigation revealed that at least four patients switched from Subutex (buprenorphine-only) to Suboxone (buprenorphine/naloxone) after the AIW. As discussed in more detail above, the DEA's expert opined that there are only two justifications for prescribing Subutex: the patient is pregnant or allergic to naloxone. These four patients are not allergic to naloxone, because if they were, they would not have been able to take Suboxone. Two of these patients are male, so they could not have been pregnant when OHHP filled their Subutex prescriptions. Therefore, these men had no justification for receiving Subutex. The other two patients are female, but their behavior indicates that they were seeking Subutex in order to abuse or divert it, not because they were pregnant. Both of these patients alternated back and forth between

⁹ Prior to the AIW, the U.S. Attorney's Office for the Southern District of West Virginia obtained an Order pursuant to 42 U.S.C. § 290dd-2(b)(2)(C) that authorized certain patient records (specifically, those related to substance abuse treatment) to be disclosed to agencies and individuals within the federal government. The Order compelled the U.S. Attorney's Office to notify the patients that their records had been seized from OHHP during the AIW.

receiving Subutex from Pennsylvania prescribers (and paying in cash) and receiving Suboxone from West Virginia prescribers (and paying with insurance). If they had been pregnant, then they would have had a legitimate reason for seeking Subutex, and they should have been able to obtain it from West Virginia prescribers. The following patients switched from Subutex to Suboxone after the AIW:

- a. **Patient J.S.A. (male):** Patient J.S.A.¹⁰ filled 16 Subutex prescriptions at OHHP prior to the AIW, from at least September 22, 2017 to November 15, 2018. Patient J.S.A. received these prescriptions from a Pennsylvania prescriber. After the AIW, Patient J.S.A. began receiving Suboxone prescriptions from West Virginia prescribers and filling them at a different West Virginia pharmacy that was much closer to his home than OHHP. The DEA's expert opined that Patient J.S.A. is clearly not allergic to naloxone, because if he were, then he would not have been able to take Suboxone. Therefore, the DEA's expert opined that Patient J.S.A. had no justification for receiving Subutex, and OHHP should not have filled his prescriptions.
- b. **Patient D.J. (male):** Patient D.J. filled 13 Subutex prescriptions at OHHP prior to the AIW, from at least April 12, 2018 to November 28, 2018. Patient D.J. received these prescriptions from various Pennsylvania prescribers. After the AIW, Patient D.J. began receiving Suboxone prescriptions from a different Pennsylvania prescriber, and he began filling them at a different West Virginia pharmacy that was closer to his home than OHHP. The DEA's expert opined that Patient D.J. is clearly not allergic to naloxone, because if he were, then he would not have been able to take Suboxone. Therefore, the DEA's expert opined that Patient D.J. had no justification for receiving Subutex, and OHHP should not have filled his prescriptions.
- c. **Patient M.D. (female):** Patient M.D. switched from Suboxone (which she received from West Virginia prescribers), to Subutex (which she received from Pennsylvania prescribers), and back to Suboxone (which she received from West Virginia prescribers). The DEA's expert opined that Patient M.D. is clearly not allergic to naloxone, because if she were, then she would not have been able to take Suboxone. Patient M.D. could not have been pregnant the entire time that she took Subutex, because she took it for a period of approximately 31 months, from June 2016 to February 2019. This is more than three times longer than a pregnancy could have lasted. Therefore, the DEA's expert opined that Patient M.D. had no justification for receiving Subutex, and OHHP should not have filled her prescriptions. OHHP filled at least 47 Subutex prescriptions for Patient M.D. from June 2017 to February 2019.
- d. **Patient K.F.:** Patient K.F. switched from Subutex (which she received from Pennsylvania prescribers) to Suboxone (which she received from West Virginia prescribers), to Subutex (which she received from Pennsylvania prescribers), and

¹⁰ See also ¶¶ 9.d.ii and 9.g.iii., *supra*.

back to Suboxone (which she received from West Virginia prescribers). Patient K.F. paid in cash for all of the Subutex prescriptions, and she paid with insurance for all of the Suboxone prescriptions. The DEA's expert opined that Patient K.F. is clearly not allergic to naloxone, because if she were, then she would not have been able to take Suboxone. The DEA's expert also opined that Patient K.F.'s Subutex prescriptions presented numerous red flags of abuse and diversion (e.g., cash payments and long distances traveled to obtain and fill prescriptions), and that OHHP should not have filled them. OHHP filled at least 11 Subutex prescriptions for Patient M.D. from August 2017 to November 2018.

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), it is my preliminary finding that OHHP's continued registration is inconsistent with the public interest. It is my preliminary finding that OHHP repeatedly dispensed controlled substances without attempting to address or resolve clear red flags of abuse and diversion, which is inconsistent with the public interest. It is also my preliminary finding, significantly in light of the rampant and deadly problem of prescription controlled substance abuse, that OHHP's continued registration during the pendency of these proceedings would constitute "an imminent danger to the public health or safety" because of the substantial likelihood that OHHP will continue to unlawfully prescribe controlled substances, thereby allowing the diversion of controlled substances, unless OHHP's DEA COR is suspended. Under the facts and circumstances described herein, it is my conclusion that OHHP's continued registration while these proceedings are pending constitutes "an imminent danger to the public health or safety." See 21 U.S.C. § 824(d). Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA COR FO3507223 is hereby suspended, effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.

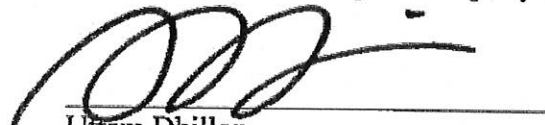
PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that OHHP possesses pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession OHHP's DEA COR FO3507223 and any unused prescription forms.

THE following procedures are available to OHHP in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, OHHP may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. See 21 C.F.R. § 1301.43(a). If OHHP fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, OHHP may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. See 21 C.F.R. § 1301.43(c).

3. Should OHHP decline to file a request for a hearing, or should OHHP request a hearing and then fail to appear at the designated hearing, OHHP shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Requests for hearing should be filed by email with the Office of Administrative Law Judges at the following address: ECF-DEA@usdoj.gov, with a copy simultaneously provided to the Government at the following address: DEA.Registration.Litigation@usdoj.gov. Other correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152. A copy of the same shall also be served on Government counsel Paul Dean and Katherine L. Steele and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrisette Drive, Springfield, Virginia 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45.



Uttam Dhillon
Acting Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Paul Dean, Senior Attorney for the Government
Katherine L. Steele, Attorney for the Government

REQUEST FOR HEARING

Any person desiring a hearing with request to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrisette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant, or attorney]

Note: Pursuant to 21 C.F.R. § 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.